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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,246	02/14/2002	Jean-Luc Gala	2752-59	5029

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EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,246	GALA ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *7,9-12,14-21,24 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,13,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 February 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, with specific further sequence elections as noted in the response in the reply filed on 5/2/05 is acknowledged. The traversal is on the ground(s) that search and examination of all of the claimed subject matter would not place an undue burden on the Examiner. This is not found persuasive. The restriction requirement sets forth a number of reasons why the search and examination of all groups, including all of the sequences recited in the claims would be an undue burden for the examiner. Each search would require the use of different key words and different literature to address the distinct subject matter. Further, the individual sequences were isolated from different organisms and would each themselves require separate sequence searches which would be an enormous burden on the examiner and on PTO resources.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-25 are pending.

3. Claims 7, 9, 10, 11, 12, 14-21, 24, and 25 are withdrawn from prosecution as being drawn to non-elected inventions.

4. Any claim which is generic in nature with regard to required SEQ ID NO has been examined as a generic claim and will be treated as a linking claim with regard to the claims which depend from it and recite specific sequences. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 4, 6, and 8. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the

limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. Regarding the claims which recite specific SEQ ID NO, any claim which recites SEQ ID NO: 65 has been examined to the extent that it recites and requires this sequence. Claims which further required additional sequences have been examined according to the further election by Applicant. For example, claim 2 has been considered as if it read that the "nucleotide probe specifically hybridizes with at least a part of a sequence selected from SEQ ID NO: 65." Likewise claims 3, 13, 22, and 23 have been examined to the extent that they require elected SEQ ID NO: 65. For claim 5 which requires the use of at least two distinct Mycobacterium species-specific us-p34 nucleotide probes (as recited in step (i) of claim 4), the claim has been examined insofar as the probes are SEQ ID NO: 65 and SEQ ID NO: 68. Claims which recite specific SEQ ID NO but do not recite or require SEQ ID NO: 65 are withdrawn from prosecution. Thus, claims 7, 9, 10, 11, 24, and 25 are withdrawn from prosecution.

6. Claims 2, 3, 5, 13, 22, and 23 are objected to for containing non-elected subject matter. In response to this office action applicant should amend the claims to be commensurate in scope with the elected sequences.

Information Disclosure Statement

7. The IDS filed 4/15/02 has been considered. A signed copy of the 1449 is included with this office action.

8. The listing of references in the specification is not a proper information disclosure statement (see p. 32-33 of the specification). 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

9. The drawings are objected to because they contain nucleic acid sequences that are not properly identified either in the drawings or in the description of the drawings with proper sequence identifiers. Applicant may remedy this problem either by amending the description of the drawings to include the sequence identifiers or by providing corrected drawing sheets that contain the proper sequence identifiers (see for example, Figure 1). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

10. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s):

The drawings include a number of nucleic acid sequences that are not identified by sequence identifier.

Further, the first sequence listed in table 3(c) on page 36 of the specification is not identified by sequence identifier.

In order to comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825), Applicant must submit a new CRF and paper copy of the Sequence Listing containing these sequences, in addition to the previously listed sequences, an amendment directing the entry of the Sequence Listing into the specification, an amendment directing the insertion of the SEQ ID NOs into the appropriate pages of the specification and a letter stating that the content of the paper and computer readable copies are the same.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 3, 5, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation in claims 3, 5, and 13 that said probe is selected from the group of sequences "represented in" the particular SEQ ID NO is indefinite because it is not clear what applicant means by the use of the transitional phrase "represented in" as a transitional phrase. That is, it is not clear what is required to meet the limitation that the probe used is the probe represented in SEQ ID NO: 65. It is not clear, for example, if applicant intends that the probe used in the claimed method must "comprise" the nucleotide sequence listed in the sequence listing or if it must "consist of" the nucleotide sequence listed in the sequence listing or some other definition. Clarification of the claim language is required. For example, a recitation that requires that the probe used in the claimed method "consists of the nucleotide sequence set forth in SEQ ID NO: 1, or the complement thereof, or the corresponding sequence wherein T has been replaced by U" would use clear transitional language.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 13, 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 13 is drawn to a method for the differential detection of Mycobacteria in a sample which utilizes amplification with SEQ ID NO: 1 and 2 (elected primer pair) and then detection with a "species specific us-p34 upstream probe," represented in elected SEQ ID NO: 65. Claim 13 includes a final process step that requires "inferring from the nucleotide duplex formed, the presence of a specific Mycobacterium species." Claims 22 and 23 are drawn to methods for differentiating from M. bovis and M. tuberculosis in a sample. Claim 22 recites that a probe that is SEQ ID NO: 65 is provided, and sets forth that this probe is "selective" for M. tuberculosis. The claim recites steps of providing the probe, reacting the probe with a sample to allow "selective formation" with the target and detecting any nucleotide duplexes containing the probe. The implication of the claim is that it is by this detection that one can infer the presence of one or the other species of Mycobacteria. Claim 23 is similar to claim 22 but recites that instant SEQ ID NO: 65 is used as a primer in the amplification reaction. (Claims 22 and 23 also recite in the alternative the use of SEQ ID NO: 66 as a probe or primer selective for M. bovis, but this alternative is withdrawn from prosecution).

The specification teaches SEQ ID NO: 65 and teaches that it was isolated from M. tuberculosis and is the region from the genome immediately upstream of the p34 coding sequence. The specification also teaches SEQ ID NO: 66 and teaches that this sequence was isolated from M. bovis and is from the region of the genome immediately upstream of the p34

coding sequence. The specification teaches that this for this region "differentiation between M. tuberculosis and M. bovis relied on a single T to C transition at position 41 of up-p34." The specification does not exemplify a method in which these full length sequences are used as primers or probes to differentiate between the two species, or when SEQ ID NO: 65 is used to differentiate M. tuberculosis in particular from all other Mycobacteria. When the SEQ ID NO: 65 is aligned to SEQ ID NO: 66, SEQ ID NO: 65 is longer than instant SEQ ID NO: 66, but instant SEQ ID NO: 66 is identical to a portion of instant SEQ ID NO: 65 except for a single nucleotide. The alignment is provided (Qy=SEQ ID NO: 65 and Db=SEQ ID NO: 66).

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Qy          1 TCATAGCAGGCCTCCTCTTGGGTCCACAACGCCCGCATCGCCTCGAGGTATTCGCGCAGC 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 TCATAGCAGGCCTCCTCTTGGGTCCACAACGCCCGCATCGCCTCGAGGTATTCGCGCAGC 60

Qy         61 ATGGTGCGGCGGCGTCCGGGTGGCACACCATGATCGACGAGCTCGTCGGTGTTCCAGCCG 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 ATGGTGCGGCGGCGTCCGGGTGGCACACCATGATCGACGAGCTCGTCGGTGTTCCAGCCG 120

Qy        121 AACCCGACCCCGACGCTGACCCGGCCGTGCGACAAATGATCCAGCGTCGCAATGCTTTTC 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 AACCCGACCCCGACGCTGACCCGGCCGTGCGACAAATGATCCAGCGTCGCAATGCTTTTC 180

Qy        181 GCCAGCGTGATCGGATCATGCTCGACCGGCAGCGCCACCGCGGTGGCAAGCCGGATCCGC 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 GCCAGCGTGATCGGATCATGCTCGACCGGCAGCGCCACCGCGGTGGCAAGCCGGATCCGC 240

Qy        241 GACGTCACCGCCGATGCTGCTCCCAGGCTCACCCACGGGTCCAACGTGCGCATATAGCGG 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 GACGTCACCGCCGATGCTGCTCCCAGGCTCACCCACGGGTCCAACGTGCGCATATAGCGG 300

Qy        301 TCGTCCGGCAGCGAAGCGTCACCCGTCGTCGGATGGGCCGCCTGGCGCTTGACCGGGATG 360
              ||||||||||||||||||||||| ||||||||||||||||||||||||||||||||||||
Db        301 TCGTCCGGCAGCGAAGCGTCACCCGCCGTCGGATGGGCCGCCTGGCGCTTGACCGGGATG 360

Qy        361 TGGGTGTGTTCGGGCACGTAAAACGTGCGAAACCCGTGGCTTTCAGCAAGTCTGGCGGCC 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 TGGGTGTGTTCGGGCACGTAAAACGTGCGAAACCCGTGGCTTTCAGCAAGTCTGGCGGCC 420

Qy        421 GCGGCCGGGGTGATGCCGCGGTCGCTGGTGAACAGCACAAGTCCGTAGTGCATGCACCGA 480
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        421 GCGGCCGGGGTGATGCCGCGGTCGCTGGTGAACAGCACAAGTCCGTAGTGCATGCACCGA 480
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Qy        481 ATTAGAACGTGTTCCACCTGCGCCGGGCAAGCGGCCGTCCAGTCGTTAATGTCGCGAGCG 540
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        481 ATTAGAACGTGTTCCACCTGCGCCGGGCAAGCGGCCGTCCAGTCGTTAATGTCGCGAGCG 540

Qy        541 CCGGTCGCTCCGGCAGCGGCACCCGAACGTGCGCTAGCGTGGTTGATCGAATCGCGTCGC 600
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        541 CCGGTCGCTCCGGCAGCGGCACCCGAACGTGCGCTAGCGTGGTTGATCGAATCGCGTCGC 600

Qy        601 CGGGAGCACAGCGTCGCACTGCACCAGT 628
              ||||||||||||||||||||||||||||
Db        601 CGGGAGCACAGCGTCGCACTGCACCAGT 628
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The instant specification and the rejected claims teach that instant SEQ ID NO: 65 is specific for M. tuberculosis. However, the post filing date art reports that instant SEQ ID NO: 65 in it's entirety is present in a sampled M. bovis specimen (see nucleotides 77929-78730 of the complete M. bovis genome reported in GenBank record having accession number BX248337,GI:31617663).

Thus, it is highly unpredictable given the high sequence homology between SEQ ID NO: 65 and SEQ ID NO: 66 and the fact that SEQ ID NO: 65 has been identified in both M. bovis how these sequences can be used to differentiate between M. bovis and M. tuberculosis in a sample.

Thus, it is concluded that it would require undue experimentation to practice the claimed invention.

15. Claims 1, 2, 3, 4, 5, 6, and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to methods for detecting Mycobacterium in samples using probes and/or primers that are selected from the "upstream p34 gene region." The specification and claims, however, do not clearly describe the "upstream p34 gene region." The specification provides the nucleotide sequence of a portion of the upstream p34 region for a variety of different species of Mycobacteria. These sequences all are of different length and have varying degrees of identity relative to one another. The specification does not define how far upstream of the p34 gene is encompassed within the "upstream p34 gene region," and as the Mycobacteria genome is circular in nature, the physical structure of the genome does not provide an delineation of what is the "upstream region." Further, the specification does not provide any written description of even which sequences within those given would be critical for the identification of sequences which would be included within the "upstream p34 gene region." Thus, the claims encompass the use of any "species-specific" probe or primer that is in the Mycobacterial genome. Furthermore, however, it is noted that even the definition of "species specific" is not clearly defined in the context of the instant specification and claims. In this rejection, this limitation is broadly interpreted to include any oligonucleotide probe or primer that would specifically hybridize to the nucleic acids of any Mycobacterium sequence specific manner, even if that molecule would hybridize to the nucleic acid of more than one Mycobacteria species. This interpretation is based upon the fact that even some of the exemplified "species specific" probes of the instant specification are contained within the sequences upstream p34 gene region of more than one species of Mycobacteria. For example, turning to SEQ ID NO: 28 which is recited in claim 3 as being a potential species specific probe, this sequence is contained both within the M. tuberculosis sequence (nucleotides 514-535 of SEQ ID NO: 65) and the M. bovis

sequence (nucleotides 514-535 of SEQ ID NO: 66). The instant specification and the rejected claims teach that instant SEQ ID NO: 65 is specific for M. tuberculosis. However, the post filing date art reports that instant SEQ ID NO: 65 in it's entirety is present in a sampled M. bovis specimen (see nucleotides 77929-78730 of the complete M. bovis genome reported in GenBank record having accession number BX248337,GI:31617663)Thus, the term "species-specific" must be broadly interpreted within the claims to encompass nucleic acids which may hybridize to more than one species of Mycobacteria.

Because the claims could encompass the use of such a hugely variant genus of nucleic acid, the claims are rejected for not providing adequate written description of the probes and primers useful for practicing the claimed invention. Claims 2, 3, and 5 recite specific SEQ ID NO, of which instant SEQ ID NO: 65 is the elected invention. However, the claims do not clearly recite the that instant SEQ ID NO: 65 is a required element of the claims. Claim 2 recites that the probe "specifically hybridizes with at least a part" of SEQ ID NO: 65. This recitation is extremely broad in nature since "at least a part" could encompass as little as one nucleotide of SEQ ID NO: 65- thus the claim encompasses the use of any probe that contains a portion that would hybridize with even very small fragments of SEQ ID NO: 65. Claims 3 and 5 recite that the probes are selected from sequences "represented in" the recited SEQ ID NO: 65. Since the specification does not define what it means for a sequence to be "represented in" a particular recitation in the sequence listing, this rejection is applied to these claims against a broad interpretation wherein "represented in" encompasses sequences with any level of homology or identity to SEQ ID NO: 65 or which comprise fragments of any length of SEQ ID

NO: 65. Thus, for all of these reasons, the instant claims are rejected for lack of written description.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 1, 2, 4, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Vannuffel et al. (1998; as cited in the IDS).

Vannuffel et al. teach that the sequence upstream to the 5' open reading frame encoding the 34 kDa mycobacterial antigenic protein p34 was sequenced in both directions in M. tuberculosis, M. bovis, M. avium, and M. paratuberculosis. Vannuffel et al. teach a PCR assay discriminating tuberculous from non-tuberculous mycobacteria wherein primers were used to amplify the upstream sequence (referred to therein as the 5'-NTR) which resulted in the amplification of PCR products of two different sizes for the two different types of mycobacteria.

Each claim rejected under Vannuffel et al. requires the provision of "at least one Mycobacterium species-specific upstream p34 gene region" probe or primer. In this rejection, this limitation is broadly interpreted to include any oligonucleotide probe or primer that would specifically hybridize to the nucleic acids of any Mycobacterium sequence specific manner, even if that molecule would hybridize to the nucleic acid of more than one Mycobacteria species.

This interpretation is based upon the fact that even some of the exemplified "species specific" probes of the instant specification are contained within the sequences upstream p34 gene region of more than one species of Mycobacteria. For example, turning to SEQ ID NO: 28 which is recited in claim 3 as being a potential species specific probe, this sequence is contained both within the M. tuberculosis sequence (nucleotides 514-535 of SEQ ID NO: 65) and the M. bovis sequence (nucleotides 514-535 of SEQ ID NO: 66). Thus, the term "species-specific" must be broadly interpreted within the claims to encompass nucleic acids which may hybridize to more than one species of Mycobacteria.

With regard to claim 1, the method taught by Vannuffel et al. anticipates the claimed invention since Vannuffel et al. provide (i) at least one Mycobacterium species-specific upstream p34 gene region nucleotide probe (which in this case is used to prime amplification), they (ii) react the probe with a sample to allow the formation of duplexes (which are then extended) and they (iii) detect the amplification products which are nucleotide duplexes containing the us-p34 nucleotide probe.

With regard to claim 2, the method anticipates the claimed invention since the nucleotide probe specifically hybridizes to "at least a part" of elected instant SEQ ID NO: 65 since "at least a part" would include any fragment of SEQ ID NO: 65, including only a single nucleotide of the sequence.

With regard to claim 4, the method taught by Vannuffel et al. anticipates the claimed invention since Vannuffel et al. provide (i) at least two Mycobacterium species-specific upstream p34 gene region nucleotide probes (which in this case are two primers used to prime amplification), they (ii) react the probe with a sample to allow the formation of duplexes (which

are then extended), they (iii) detect the amplification products which are nucleotide duplexes containing the us-p34 nucleotide probe, and (iv) they infer from the length of the amplification products whether the Mycobacteria are tuberculous or non-tuberculous mycobacteria.

With regard to claims 6 and 8, the method taught by Vannuffel et al. anticipates the claimed invention since Vannuffel et al. provide (i) at least one suitable Mycobacterium species-specific upstream p34 gene region nucleotide primer pair, they (ii) react the primer pair with a sample to allow the formation of duplexes (which are then extended), they (iii) detect the amplification products which are nucleotide duplexes containing the us-p34 nucleotide probe, and (iv) they infer from the length of the amplification products whether the Mycobacteria are tuberculous or non-tuberculous mycobacteria.

Conclusion

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Wednesday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached by calling (571) 272-0745.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Juliet C. Switzer
Primary Examiner
Art Unit 1634

July 25, 2005